



JPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF MAILING BY FIRST-CLASS MAIL

I hereby certify that this correspondence and the documents referred to as enclosed therein are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 27, 2004.

Kim H. Lu

Kimberly H. Lu
Reg. No. 51,973

Application of:	Bajaj, S. Paul	Group No.:	1653
Serial No.:	10/662,784	Atty. Docket No.:	66153-39722
Filed:	September 15, 2003		
For:	<i>REGION OF FACTOR IXa PROTEASE DOMAIN THAT INTERACTS WITH FACTOR VIIIa AND METHODS THEREFOR</i>		
Examiner:	Not Yet Assigned		

Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

HONORABLE SIR:

The present application is a continuation in part of U.S. application no. 09/584,866 (Patent No. 6,624,289 B1). Pursuant to the MPEP § 609.I.A.2, Applicant is not providing copies of the references listed in the enclosed Information Disclosure Statement. According to this section of the MPEP, references that have been considered by the U.S.P.T.O. in the parent application need not be resubmitted.

Respectfully submitted,

Kim H. Lu

Kimberly H. Lu, Reg. #51,973
Thompson Coburn LLP
One US Bank Plaza
St. Louis, Missouri 63101
Telephone: 314-552-6000
Fax: 314-552-7000

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
66153-39722

In Re Application Of:

Bajaj, S. Paul

Serial No.
10/662,784

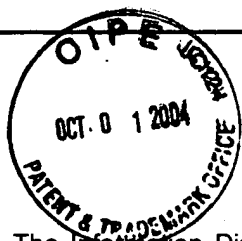
Filing Date
September 15, 2003

Examiner
Not Yet Assigned

Group Art Unit
1653

Title:

REGION OF FACTOR IXa PROTEASE DOMAIN THAT INTERACTS WITH FACTOR VIIIa AND METHODS THEREFOR



Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

OR

☐ the fee set forth in 37 CFR 1.17(p).

Per 37 CFR §1.98(d), copies of the references cited in the accompanying Information Disclosure Statement are not provided herewith because such references were previously cited by or submitted to the Patent and Trademark Office in a parent application to which this application relies upon for an earlier filing date under 35 U.S.C. §120.

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
66153-39722

In Re Application:

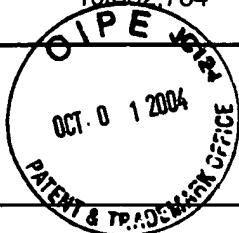
Bajaj, S. Paul

Serial No.
10/662,784

Filing Date
September 15, 2003

Examiner
Not Yet Assigned

Group Art Unit
1653



Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge and credit Deposit Account No. 20-0823 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of _____
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

Certificate of Transmission by Facsimile*

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. _____) on _____

(Date)

Signature

Typed or Printed Name of Person Signing Certificate

Certificate of Mailing by First-Class Mail

I certify that this document and fee is being deposited on September 27, 2004, with the U.S. Postal Service as First-Class Mail under 37 C.F.R. 1.8 and addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature of Person Mailing Correspondence

Kimberly H. Lu

Typed or Printed Name of Person Mailing Certificate

***This certificate may only be used if paying by deposit account.**

Signature
Kimberly H. Lu, Reg. No. 51,973
Thompson Coburn LLP
One US Bank Plaza
St. Louis, Missouri 63101-9928
314-552-6000
314-552-7000 FAX

Dated: September 27, 2004

Customer No: 021888

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

1

of

5

Complete if Known

Application Number

10/662,784

Filing Date

September 15, 2003

First Named Inventor

Bajaj, S. Paul

Art Unit

1653

Examiner Name

Not Yet Assigned

Attorney Docket Number

66153-39722

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 5,932,706	08-03-1999	Mertens et al.	
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO 93/09804	05-27-1993	Griffin et al.		
		WO 94/25482	11-10-1994	Evans et al.		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		MATHUR et al., Protease and EGF1 domains of factor IXa play distinct roles in binding to factor VIIIa, J. Biol. Chem., 1999, 274(26): 18477-18486	
		YOSHITAKE et al., Nucleotide sequence of the gene for human factor IX (antihemophilic factor B), Biochemistry, 1985, 24: 3736-3750	
		DISCIPIO et al., Activation of human factor IX (Christmas factor), J. Clin. Invest., 1978, 61: 1528-1538	
		DAVIE et al., The coagulation cascade: initiation, maintenance, and regulation, Biochemistry, 1991, 30: 10363-10370	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/662,784	
			Filing Date	September 15, 2003	
			First Named Inventor	Bajaj, S. Paul	
			Group Art Unit	1653	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	5	Attorney Docket Number	66153-39722

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BRANDSTETTER et al., X-ray structure of clotting factor IXa: active site and module structure related to Xase activity and hemophilia B., Proc. Natl. Acad. Sci. USA, 1995, 92: 9796-9800	
		BANNER et al., The crystal structure of the complex of blood coagulation factor VIIa with soluble tissue factor, Nature, 1996, 380: 41-46	
		SABHARWAL et al., Interaction of calcium with native and decarboxylated human factor X. Effect of proteolysis in the autolysis loop on catalytic efficiency and factor Va binding, J. Biol. Chem., 1997, 272: 22037-22045	
		RAO et al., The structure of a Ca(2+)-binding epidermal growth factor-like domain: its role in protein-protein interactions, Cell, 1995, 82: 131-141	
		BAJAJ et al., Antibody-probed conformational transitions in the protease domain of human factor IX upon calcium binding and zymogen activation: putative high-affinity Ca(2+)-binding site in the protease domain, Proc. Natl. Acad. Sci. USA, 1992, 89: 152-156	
		FREEDMAN et al., Identification of the phospholipid binding site in the vitamin K-dependent blood coagulation protein factor IX, J. Biol. Chem., 1996, 271: 16227-16236	
		ZHONG et al., First epidermal growth factor-like domain of human blood coagulation factor IX is required for its activation by factor VIIa/tissue factor but not by factor XIa, Proc. Natl. Acad. Sci. USA, 1994, 91: 3574-3578	
		LENTING et al., Ca ²⁺ binding to the first epidermal growth factor-like domain of human blood coagulation factor IX promotes enzyme activity and factor VIII light chain binding, J. Biol. Chem., 1996, 271: 25332-25337	
		AHMED et al., The role of the second growth-factor domain of human factor IXa in binding to platelets and in factor-X activation, Biochem. J., 1995, 310: 427-431	
		ASTERMARK et al., The gamma-carboxyglutamic acid and epidermal growth factor-like modules of factor IXa beta. Effects on the serine protease module and factor X activation, J. Biol. Chem., 1994, 269: 3682-3689	
		O'BRIEN et al., Localization of factor IXa and factor VIIIa interactive sites, J. Biol. Chem., 1995, 270: 27087-27092	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/662,784	
			Filing Date	September 15, 2003	
			First Named Inventor	Bajaj, S. Paul	
			Group Art Unit	1653	
			Examiner Name	Not Yet Assigned	
Sheet	3	of	5	Attorney Docket Number	66153-39722

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BAJAJ et al., Human factor IX and factor IXa, Methods Enzymol, 1993, 222: 96-128	
		MATHUR et al., Interaction of factor IXa with factor VIIIa. Effects of protease domain Ca2+ binding site, proteolysis in the autolysis loop, phospholipids, and factor X, J. Biol. Chem., 1997, 272: 23418-23426	
		HAMAGUCHI et al., The role of amino-terminal residues of the heavy chain of factor IXa in the binding of its cofactor, factor VIIIa, Blood, 1994, 84: 1837-1842	
		RIPKA et al., Peptidomimetic design, Current Opin. Chem. Biol., 1998, 2(4): 441-452	
		WOOD et al., Expression of active human factor VIII from recombinant DNA clones, Nature, 1984, 312: 330-337	
		VEHAR et al., Structure of human factor VIII, Nature, 1984, 312: 337-342	
		BAJAJ et al., A simplified procedure for purification of human prothrombin, factor IX and factor X, Prep. Biochem., 1981, 11: 397-412	
		ZHONG and BAJAJ, A PCR-based method for site-specific domain replacement that does not require restriction recognition sequences, Biotechniques, 1993, 15: 874-878	
		USHARANI et al., Characterization of three abnormal factor IX variants (Bm Lake Elsinore, Long Beach, and Los Angeles) of hemophilia-evidence for defects affecting the latent catalytic site, J. Clin. Invest., 1985, 75: 76-83	
		LINK and CASTELLINO, The activation of bovine factor X by bovine factor Xa, Arch. Biochem. Biophys., 1982, 215: 215-221	
		VAN DIEIJEN et al., The role of phospholipids and factor VIIIa in the activation of bovine factor X, J. Biol. Chem. 1981, 256: 3433-3442	

Examiner Signature	Date Considered
--------------------	-----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/662,784	
			Filing Date	September 15, 2003	
			First Named Inventor	Bajaj, S. Paul	
			Group Art Unit	1653	
			Examiner Name	Not Yet Assigned	
Sheet	4	of	5	Attorney Docket Number	66153-39722

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		FAY and KOSHIBU, The A2 subunit of factor VIIIa modulates the active site of factor IXa, J. Biol. Chem., 1998, 273: 19049-19054	
		KRISHNASWAMY, The interaction of human factor VIIa with tissue factor, J. Biol. Chem., 1992, 267: 23696-23706	
		HALFMAN, Concentrations of binding protein and labeled analyte that are appropriate for measuring at any analyte concentration range in radioimmunoassays, Meth. Enzymol., 1981, 74: 481-508	
		BYLUND and TOEWS, Radioligand binding methods: practical guide and tips, Am. J. Physiol., 1993, 265: L421-L42	
		REES et al., The role of beta-hydroxyaspartate and adjacent carboxylate residues in the first EGF domain of human factor XI, EMBO J., 1988, 7: 2053-2061	
		HUGHES et al., Tyrosine 69 of the first epidermal growth factor-like domain human factor IX is essential for clotting activity, J. Biol. Chem., 1993, 268: 17727-17733	
		FRAZIER et al., Mapping of monoclonal antibodies to human factor IX, Blood, 1989, 74: 971-977	
		LUDWIG et al., Hemophilia B caused by five different nondeletion mutations in the protease domain of factor IX, Blood, 1992, 79: 1225-1232	
		GIANNELLI et al., Haemophilia B: database of point mutations and short additions and deletions—eighth edition, Nucleic Acids Res., 1998, 26: 265-268	
		MATHER et al., The 2.8 A crystal structure of Gla-domainless activated protein C, EMBO J., 1996, 15: 6822-6831	
		BAJAJ et al., Synthesis and expression of tissue factor pathway inhibitor by serum-stimulated fibroblasts, vascular smooth muscle cells and cardiac myocytes, Thrombos. Haemostas, 1999, 82: 1663-1672	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/662,784	
			Filing Date	September 15, 2003	
			First Named Inventor	Bajaj, S. Paul	
			Group Art Unit	1653	
			Examiner Name	Not Yet Assigned	
Sheet	5	of	5	Attorney Docket Number	66153-39722

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		CHANG et al., Changing residue 338 in human factor IX from arginine to alanine causes an increase in catalytic activity, J. Biol. Chem., 1998, 273: 12089-12094	
		LIN et al., Expression and characterization of human factor IX and factor IX-factor X chimeras in mouse C127 cells, J. Biol. Chem., 1990, 265: 144-150	
		CHANG et al., Replacing the first epidermal growth factor-like domain of factor IX with that of factor VII enhances activity in vitro and in canine hemophilia B, J. Clin. Invest., 1997, 100: 886-892	
		SPITZER et al., Factor IX Hollywood: substitution of Pro55 by Ala in the first epidermal growth factor-like domain, Blood, 1990, 76: 1530-1537	
		McCORD et al., Characterization of the functional defect in factor IX Alabama, J. Biol. Chem., 1990, 265: 10250-10254	
		CHRISTOPHE et al., Blood coagulation factor IX residues Glu78 and Arg94 provide a link between both epidermal growth factor-like domains that is crucial in the interaction with factor VIII light chain, J. Biol. Chem., 1998, 273: 222-227	
		LARSON et al., Structural integrity of the gamma-carboxyglutamic acid domain of human blood coagulation factor IXa is required for its binding to cofactor VIIIa, J. Biol. Chem., 1996, 271: 3869-3876	
		SABHARWAL et al., High affinity Ca(2+)-binding site in the serine protease domain of human factor VIIa and its role in tissue factor binding and development of catalytic activity, J. Biol. Chem., 1995, 270: 15523-15530	
		BAJAJ et al., A monoclonal antibody to factor IX that inhibits the factor VII:Ca potentiation of factor X activation, J. Biol. Chem., 1985, 260: 11574-11580	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.